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ABSTRACT BOOK

57th Annual Meeting and Scientific Sessions Saturday, June 21 — Tuesday, June 24, 1997

Hynes Convention Center Boston, Massachusetts

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DIAEAZ 46 Supplement (1) 1A-434 (1997) JISSN 0012-1797 Pramlintide, an Analog of Human Amylin Improves Glycemic Control in Patients with Type II Diabetes Requiring Insulin. ROBERT THOMPSON*1, LEEANNE PEARSON*1, STEVEN SCHOENFELD*1, ORVILLE KOLTERMAN*1. San Diego, CA

The effects of 4 weeks of subcutaneous administration of pramlintide, (Pr) an analog of human amylin, on glycemic control in 203 patients with Type II diabetes mellitus requiring insulin were examined in a randomized, double-blind, placebo-controlled, parallel-group trial. Statistically significant reductions in serum fructosamine concentration were observed in the Pr 30 μg QID group (17.5±4.9 μmol/L), the Pr 60 μg TID group (24.1±4.9 μmol/L) and the Pr 60 μg QID group (22.6±4.1 μmol/L) compared to placebo (PBO) (3.5±3.8 µmol/L). There also were statistically significant shifts in the proportion of patients with an abnormal serum fructosamine concentration at baseline that normalized at Week 4 within the Pr 60 µg TID group (28%) and the Pr 60 μg QID group (31%) compared to PBO (10%). Consistent with the reduction in fructosamine, there were also statistically significant reductions in HbA_{lc} in the Pr 30 μg QID group (0.53±0.07%), the Pr 60 µg TID group (0.58±0.07%) and the Pr 60 µg QID group (0.51±0.08%) compared to placebo (0.27±0.08%). Based on RBC lifespan, and assuming stable glycemic control, these reductions in HbAlc in the Pr groups should increase over the following 2-3 months. The reductions in fructosamine and HbA1c were accompanied by a statistically significant reduction in fasting total and LDL cholesterol. In contrast to treatment with insulin alone, there were trends towards decreased body weight in the Pr 60 μg TID and 60 μg QID groups. Furthermore, the incidence of hypoglycemia was no greater in any Pr group than in placebo. In conclusion, measurement of similar changes in both serum fructosamine concentration and HbA_{lc} suggests that pramlintide therapy for 28 days improves glycemic control in patients with Type II diabetes mellitus requiring insulin.

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Approved for use through 10/31/2002. OMB 0651-0032
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